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Pluvicto (*lutetium (^{177}Lu) vipivotide tetraxetan*)

An overview of Pluvicto and why it is authorised in the EU

What is Pluvicto and what is it used for?

Pluvicto is a medicine used to treat cancer of the prostate (a gland of the male reproductive system). It is used when the cancer is metastatic (spreading to other parts of the body), progressive, castration-resistant (worsens despite treatment to lower levels of the male sex hormone testosterone), and the cancer cells have a protein called prostate-specific membrane antigen (PSMA) on their surface (PSMA-positive prostate cancer).

Pluvicto is used together with androgen deprivation therapy (treatment to lower male sex hormones) in adults previously treated with androgen receptor pathway inhibitors (medicines for prostate cancer), and a medicine of the group of cancer medicines known as taxanes. Androgen receptor pathway inhibitors may also be added to Pluvicto and androgen deprivation therapy.

Pluvicto is a radiopharmaceutical (a medicine that gives off a small amount of radioactivity) that contains the active substance lutetium (^{177}Lu) vipivotide tetraxetan.

How is Pluvicto used?

Because Pluvicto gives off some radioactivity, it is only used in special controlled areas and must be given to patients by healthcare professionals qualified and authorised to use radiopharmaceuticals.

Before starting treatment, the doctor will check that the patient's tumours have PSMA on their cell surfaces with a positron emission tomography (PET) scan.

Pluvicto is given by injection or infusion (drip) into a vein once every 6 weeks for up to a total of 6 doses.

Blood tests will be done before and during treatment to detect certain side effects early. Based on the results of these tests and any side effects the patient may develop, the doctor may decide to delay, change or stop treatment with Pluvicto.

For more information about Pluvicto, including precautions that should be taken to limit radioactivity exposure to patients and people around them, see the package leaflet or contact your doctor or pharmacist.

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How does Pluvicto work?

Pluvicto works by attaching to the PSMA protein found on the surface of the prostate cancer cells. The radioactivity it emits kills the tumour cells it is attached to but has little effect on neighbouring cells.

What benefits of Pluvicto have been shown in studies?

Pluvicto was shown to be effective at increasing the time patients live without their cancer getting worse and the time they live overall.

In a main study involving 831 patients with progressive, metastatic, castration-resistant and PSMA-positive prostate cancer, 551 patients were treated with Pluvicto together with other treatments for prostate cancer (best standard of care) and 280 were given standard of care only. The study showed that patients given Pluvicto lived for 8.7 months on average without their cancer getting worse, compared with 3.4 months on average for those treated with standard of care only. In addition, on average, patients treated with Pluvicto lived 15.3 months, while those receiving standard of care lived for 11.3 months.

What are the risks associated with Pluvicto?

The most common side effects with Pluvicto (which may affect more than 1 in 10 people) are tiredness, dry mouth, nausea (feeling sick), anaemia (low levels of red blood cells), decreased appetite and constipation.

The most common serious side effects (which may affect up to 1 in 20 people) are anaemia, thrombocytopenia (low levels of blood platelets), lymphopenia (low levels of lymphocytes, a type of white blood cell) and tiredness.

For the full list of side effects and restrictions of Pluvicto, see the package leaflet.

Why is Pluvicto authorised in the EU?

Pluvicto has been shown to increase both the time people with progressive, metastatic, castration-resistant and PSMA-positive prostate cancer live without their disease getting worse and the time they live overall. Although treatment with Pluvicto may cause more side effects than standard of care, they are considered manageable. The European Medicines Agency also noted the limited treatment options available for patients with this type of cancer. The Agency therefore decided that Pluvicto's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Pluvicto?

The company that markets Pluvicto will ensure that patient given this medicine have access to a patient guide containing important information on the risk of radioactivity and precautions they should take to limit exposure to themselves and people around them.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Pluvicto have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Pluvicto are continuously monitored. Suspected side effects reported with Pluvicto are carefully evaluated and any necessary action taken to protect patients.

Other information about Pluvicto

Pluvicto received a marketing authorisation valid throughout the EU on 09 December 2022.

Further information on Pluvicto can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/pluvicto

This overview was last updated in 12-2022.